Virginia Cornish

Serial No.:

10/056,874

Filed: Page 9 January 24, 2002

Remarks

Claims 1-41 are pending in the subject application. By this amendment, applicant has canceled claims 2-4, 6-14, 23-29, and 41, added claims 55-56, and amended claims 1 and 5. Accordingly, claims 1, 5, 15-22, 30-40, and 55-56 will be pending upon entry of this amendment.

Applicant notes that the Examiner has reviewed all original claims 1-54 in requiring restriction despite claims 42-54 having been canceled in applicant's Preliminary Amendment. By this amendment applicant has introduced back original claims 52 and 53 as new claims 55 and 56, and understands these claims to be part of Group V.

Support for amended claim 1 may be found, inter alia, on page 9, lines 3 to 22.

Restriction Requirement

In the June 16, 2004 Office Action, the Examiner required restriction to one of the following allegedly independent and distinct inventions characterized by the following Groups I-VI:

- Claims 1-5 and 41-46, drawn to a product described as a I. "compound having the formula H1-Y-H2";
- Claims 6-13 and 47-50, drawn to a product described as "a II. complex between the compound of claim 1 and a fusion protein";

Virginia Cornish

Serial No.:

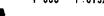
10/056,874 January 24, 2002

Filed: Page 10

> III. Claims 14-22 and 51, drawn to a product described as a cell "comprising the complex of claim 6" or "comprising a DNA sequence which on transcription gives rise to a first fusion protein";

- IV. Claims 23-29, drawn to a method for "dimerizing two fusion proteins inside a cell";
- V. Claims 30-40 and 52-53, drawn to a method for "identifying a molecule that binds a known target in a cell from a pool of candidate molecules; and
- VI. Claim 54, drawn to a product described as a "new protein cloned by the method of claim 53.

In paragraph 3 of the June 16, 2004 Office Action, the Examiner alleged that Groups I-VI represent separate and patentably distinct inventions. The Examiner also alleged that Groups IV-V are drawn to different methods and that Groups I-III and VI are drawn to different products (i.e., e.g., which are directed to different purposes, use different materials, recite different method or process steps for the preparation of different product(s), screening of different characteristics, such as different binding affinities, different biochemical reaction conditions, etc. or lead to different final results). Further, the Examiner alleged that the groups that describe these products and methods allegedly have different issues regarding patentability and enablement, and represent patentably distinct subject matter, which merits separate and burdensome searches. Finally, the Examiner alleged that art anticipating or rendering obvious each of the above-identified



Virginia Cornish

Serial No.:

10/056,874 January 24, 2002

Filed: Page 11

groups respectively would not necessarily anticipate or render obvious another group, because they are drawn to different inventions that have different distinguishing features.

In paragraph 4 of the June 16, 2004 Office Action, the Examiner alleged that Groups IV-V represent patentably distinct methods. The Examiner alleged that the methods are distinct because they use different steps, require different reagents and/or will produce different results. Further, the Examiner alleged that the method of Group V employs a library-screening step, which is not required by the method of Group IV. The Examiner alleged that as a result, Group V requires a different reagent (i.e., a library) that is not required by Group IV. Finally, the Examiner alleged that Groups IV and V have different issues regarding patentability and enablement and represent patentably distinct subject matter.

In paragraph 5 of the June 16, 2004 Office Action, the Examiner alleged that Groups I-III and VI represent patentably distinct products. The Examiner alleged that Groups I-III and VI represent separate and patentably distinct products because they differ in respect to their properties, their use and the synthetic methodology for making them. The Examiner alleged that Group III is drawn to a "cell", which requires different reagents and/or materials than Groups I, II and VI (i.e., the other groups don't require cells). In addition, the Examiner alleged that Group II is drawn to a complex, which requires different reagents and/or materials than the groups I and VI (i.e., they don't require complexes). Further, the Examiner alleged that Group VI is drawn to a "protein", which requires different reagents and/or materials than Group I. The Examiner also alleged that art anticipating or rendering obvious each of the above-identified groups respectively

Virginia Cornish

Serial No.: Filed:

10/056,874 January 24, 2002

Page 12

would not necessarily anticipate or render obvious another group, because they are drawn to different inventions that have different distinguishing features and/or characteristics. Finally, the Examiner alleged that Groups I-III and VI have different issues regarding patentability and enablement and represent patentably distinct subject matter.

In paragraph 6 of the June 16, 2004 Office Action, the Examiner alleged that if applicant was to argue that any of Groups I-III and VI are somehow related to Groups IV-V as product and process of the inventions allegedly still be shown can distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). The Examiner concludes that in the instant case, the compounds can allegedly be used for a materially different process of using that product, such as in drug treatment therapies or in the materially different processes disclosed in Groups III and IV.

Species Election

In paragraph 13 of the June 16, 2004 Office Action, the Examiner stated that if applicant elects the invention of Group V, the Examiner required the applicant to elect from the following patentably distinct species. The Examiner alleged that Claim 30 is generic.

The Examiner required the applicant to elect from Subgroup 1: a

Virginia Cornish

Serial No.:

10/056,874

Filed: Page 13 January 24, 2002

species of covalent candidate (e.g.. see claim 30.) The Examiner required the applicant to elect, for the purposes of search, a single species of covalent candidate. The Examiner required that the election result in a particularly defined core structure that is shared by all candidate molecules. Further, the Examiner required that in defining this core structure, all variable groups should be defined (i.e. all atoms and bonds shown) as much as possible. However, the Examiner required that if no common core structure exists, a representative example must be elected by the applicant.

The Examiner required the applicant to elect from Subgroup 2: a species of substrate (e.g., see claim 30.) The Examiner required that the applicant must elect, for the purposes of search, a single species of substrate.

The Examiner required that the applicant elect from Subgroup 3: a species of target receptor (e.g., see claim 30.) from either A. Known (e.g., see claim 30) or B. Unknown (e.g., see claim 38.) The Examiner required the applicant to elect, for the purposes of search, a single species of target receptor. Further, the Examiner required the applicant to elect from A or B above. In addition, the Examiner required the applicant to identify the target receptor if known or identify if it comes from a genomicDNA, cDNA or synthetic DNA if unknown (e.g., see claim 53).

The Examiner required the applicant to elect from Subgroup 4: a species of first fusion protein (e.g., see claim 30.) The Examiner required the applicant to elect, for the purposes of search, a sinele species of fusion protein e.g., eDHFR-LexA.

Virginia Cornish

10/056,874

Serial No.: Filed: Page 14

January 24, 2002

The Examiner required the applicant elect from Subgroup 5: a species of second fusion protein (e.g., see claim 30.) The Examiner required the applicant to elect, for the purposes of search, a single species of fusion protein e.g., R61-B42.

The Examiner required the applicant to elect from Subgroup 6: a species of cell (e.g., see claim 31.) The Examiner required the applicant to elect, for the purposes of search, a single species of cell e.g., yeast.

The Examiner required the applicant to elect from Subgroup 7: a species of reporter gene (e.g., see claim 30.) The Examiner required the applicant to elect, for the purposes of search, a single species of reporter gene e.g., lacZ reporter gene.

The Examiner required the applicant to elect from Subgroup 7 [sic]: a species of binding (e.g., see claim 30) either A. Competitive i.e., in presence of random small molecules for competitive binding (e.g., see claim 37) or B. Non-competitive i.e., NOT in presence of random small molecules for competitive binding (e.g., see claim 30). The Examiner required the applicant to elect, for the purposes of search, a single species of binding from either A or B above.

Applicant's Response

In response, applicant hereby elects, with traverse, the invention of the claims identified as Group V, i.e., claims 30-40, and new claims 55-56, drawn to a method.



Virginia Cornish

Serial No.: Filed:

10/056,874 January 24, 2002

Page 15

Pursuant to paragraph 13 of the June 16, 2004 Office Action, applicant elects a species for each of the eight (8) subgroups for initial examination as detailed below:

For Examiner's Subgroup 1, no species can be designated for the method of claim 30 because claim 30 recites a method of identifying the unknown species. The species used in applicant's examples is a Methotrexate moiety. Methotrexate can be used as the species for initial examination of a known ligand of claim 33.

For Subgroup 2, applicant elects for intial examination the cephen moiety disclosed on page 49 of the specification which binds to the pencillin-binding protein.

For Subgroup 3, applicant elects for initial examination: A) the known target receptor penicillin-binding-protein for claim 30; and B) the unknown cDNA derived receptor for claim 38.

From Subgroup 4, applicant elects for initial examination the fusion protein eDHFR-LexA as the species of the first fusion protein.

For Subgroup 5, applicant elects for initial examination the fusion protein R61-B42 as the species of the second fusion protein.

For Subgroup 6, applicant elects for initial examination a yeast

Virginia Cornish

Serial No.: Filed:

10/056,874 January 24, 2002

Page 16

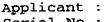
cell as a species of cell.

For Subgroup 7, applicant elects for initial examination a lacz reporter gene as a species of reporter gene.

For Subgroup 8, applicant elects for initial examination a competitive binding as a species of binding.

Applicant, however, respectfully requests that the Examiner reconsider and withdraw the restriction requirement. Under 35 U.S.C. §121, restriction may be required if two or more independent and distinct inventions are claimed in one application.

The inventions of claims 1, 5, 15-22, 30-40, and 55-56 are not independent. Under M.P.E.P. \$802.01, "independent" means there is no disclosed relationship between the subjects disclosed. The methods of elected Group V use the products of claims 1 and 5 (Group I) and the cells expressing fusion proteins of claims 15-22 (Group III.) The methods of claims 30-40 and 55-56 use the compounds described in claims 1 and 5 to screen a pool of candidate molecules for binding to exogenous fusion proteins expressed in the cells of claims 15-22. The methods of claims 30-40 and 55-56 can be practiced with the compound structure described in claims 1 and 5 and the cells described in claims 15-22 to determine which molecules bind to a known target receptor. Applicant therefore maintains that claims 1, 5, 15-22, 30-40, and 55-56 are not independent and restriction is not proper.



Virginia Cornish

Serial No.:

10/056,874

Filed: Page 17 January 24, 2002

Furthermore, under MPEP §809.03, restriction of claims which are "linked" by one or more "linking" claims inseparable therefrom is improper. A claim to practicing a process "links" apparatus and process claims, see MPEP §809.03(C). Claims 30-40, and 55-56 are drawn to processes employing the compounds and cells described in claims 1, 5, and 15-22. Thus, claims 1, 5, and 15-22 are "linked" to claims 30-40, and 55-56. Under MPEP §809.04, if a linking claim is allowed, the examiner must examine claims to the nonelected inventions that are linked to the elected invention by such allowed linking claim.

Furthermore, under MPEP §803, there are two criteria for a proper restriction requirement: 1) the invention must be independent or distinct (discussed above), and 2) there must be a serious burden on the Examiner if restriction is required. MPEP §803 unambiguously provides that "[i]f the search and examination of an entire application can be made without serious burden, the examiner must examine it on the merits, even though it includes claims to independent and distinct inventions." Applicant respectfully submits that there would not be a serious burden on the Examiner if restriction is not required between claims 1, 5, 15-22, 30-40, and 55-56 because a search for prior art material to the patentability of the claims of any of elected claims 30-40, and 55-56 would necessarily turn up the prior art material to the patentability of the claims of Group 1, 5, and 15-22. The method described in claims 30-40, and 55-56 employs the products of claims 1, 5, and 15-22 as components in the method. A search for prior art material to this method would turn up components of that method, including the products of claims 1, 5, and 15-22. Since there is no burden on the Examiner to examine claims 1, 5, 15-22, 30-40, and 55-56 together

Virginia Cornish

Serial No.:

10/056,874 January 24, 2002

Page 18

in the subject application, it is therefore submitted that claims 1, 5, 15-22, 30-40, and 55-56 should be examined on the merits.

In view of the foregoing, applicant maintains that the June 16, 2004 restriction requirement is not proper under 35 U.S.C. §121 and respectfully request that the Examiner reconsider and withdraw the requirement.

If a telephone interview would be of assistance in advancing prosecution of the subject application, applicant's undersigned attorneys invites the Examiner to telephone them at the number provided below.

No fee is deemed necessary in connection with the filing of this Amendment. However, if any fee is required, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 03-3125.

Respectfully submitted,

I hereby certify that this correspondence is being deposited this date with the U.S. Postal correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450

John P. Whote Reg. No. 28,678 Gary J. Gershik Reg. No. 39,992

John P. White

Registration No. 28,678

Gary J. Gershik

Registration No. 39,992 Attorneys for Applicant

Cooper & Dunham LLP

1185 Avenue of the Americas New York, New York 10036

(212) 278-0400